

## Office of the Attorney General Robert E. Cooper, Jr.

## **Department of Commerce and Insurance Commissioner Leslie Shechter Newman**

## **NEWS RELEASE**

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## TENNESSEE ANNOUNCES 30-STATE, \$8 MILLION AGREEMENT WITH BAYER CORP. REGARDING INADEQUATE RISK DISCLOSURE

Tennessee Attorney General Bob Cooper today announced Tennessee has joined a multistate agreement with Bayer Corporation over its questionable marketing of Baycol, a drug used to lower cholesterol withdrawn from the market in 2001.

Tennessee will receive \$200,000 as its share of the \$8 million agreement to be paid to 30 states. In addition, the company has agreed to abide by Tennessee Consumer Protection laws.

The states have alleged Bayer failed to adequately disclose safety risks associated with Baycol. Those risks included muscle weakness and a more serious muscle deteriorating disease.

The judgment, filed today in Circuit Court for Davidson County, requires Bayer to register most of its clinical studies and then post the results at the end of each study. The judgment also requires Bayer to comply with all marketing, sales and promotional laws. It is also prohibited from making any misleading claims about its products sold in the United States.

"We are pleased with the agreement which will help protect consumers from potentially harmful medications," Attorney General Cooper said. "We want to ensure Tennessee doctors receive all of the facts before prescribing medications and that consumers receive all the facts

before making a decision to take prescription medications."

In May of 1998, Bayer introduced into the United States market Baycol, a "statin" cholesterol-lowering drug. All statins carry a known risk of myopathy (a weakening of the muscles) and rhabdomyolysis (a more serious muscular disease). Through post-marketing surveillance of its product, Bayer learned that the risk for Baycol turned out to be significantly higher compared to other statins, particularly at higher doses and when combined with genfibrozil, another cholesterol-lowering drug. The Attorneys General allege that while Bayer informed the US Food and Drug Administration about these adverse effects, Bayer failed to adequately warn prescribing physicians and consumers about them.

Bayer denies any wrongdoing, and on Aug. 7, 2001, the company voluntarily withdrew Baycol from the market.